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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,165	12/22/2000	Richard W. Tseng	034827-0302	1234

7590 11/22/2002
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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT PAPER NUMBER

1637

DATE MAILED: 11/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/747,165

Applicant(s)

TSENG ET AL.

Examiner

Jeffrey Fredman

Art Unit

1637

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 November 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on 12 November 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.


NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.Claim(s) objected to: None.Claim(s) rejected: 1-13.Claim(s) withdrawn from consideration: None.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____


Jeffrey Fredman
Primary Examiner
Art Unit: 1637

Continuation of 5. does NOT place the application in condition for allowance because: The request for reconsideration makes several separate arguments. First, the request argues that "real time PCR" is a phrase defined by the art as meaning measurement of PCR during logarithmic phase rather than at the end of PCR. However, this definition does not appear in the specification of this application. So Applicant attempts to rely upon the art to define the term. However, the method steps between the two real time PCR methods cited previously are significantly different. So when Applicant uses the terms, the *metes and bounds are unclear because, for example, it is not clear whether this term is limited to Real-time Taqman assays, to lightcycler type assays or to some other assay type.* So this rejection is maintained.

Applicant then argues that the invention is distinct from Mensink because the primers selected are different, though they are selected from the well known BCR and ABL coding regions taught by the cited references Hariharan and Shtivelman. In particular, Applicant argues that there are no homologies between the primers. This argument is incorrect. The primers are all drawn from the identical sequence for the identical purpose, so an ordinary practitioner would have been motivated to select primes using software expressly disclosed by Mensink, the Primer Express software, where the software selects primers based on input criteria of desired Tm, length, and other well known parameters. The particular primers selected by Applicant are similar in Tm, in length, and are drawn from known prior art sequences for the same purpose as the Mensink primers. They are functionally homologous in the detection of BCR-ABL and structurally homologous in being drawn from the same prior art known sequences.. In the present fact pattern, the expected functional equivalence of every member species of the genus of probes, suggests the homologous oligonucleotides. This suggestion, combined with the ability of a computer or scientist to completely define each and every species member solely using the prior art supports the position that each oligonucleotide is *prima facie* obvious over a prior art teaching of the entire sequence from which the oligonucleotide is derived.

The CAFC applied the same line of reasoning in *Merck & Co. v. Biocraft Laboratories, Inc.*, 874 F.2d 804, 807 (CAFC 1989) where the selection of a particular compound out of 1200 possible prior art compounds in the prior art genus was determined to be obvious. In *Merck*, the obviousness was based in part on the structural similarity of the different compounds, but was substantially based upon the Court's understanding that each and every compound in the genus would have been expected to function. The court noted that "any of the 1200 disclosed combinations will produce a diuretic formulation with desirable sodium and potassium eliminating properties." In the current case, for example, selection of probes about the 21 nucleotides of Mensink using the software expressly taught by Mensink, would result in significantly fewer combinations than those in *Merck*, yielding a situation more supportive of obviousness than *Merck*.

Applicant then cites the He reference and Robertson and Waller to argue that primer selection is trial and error. First, this citation is inappropriate and untimely, since the references were never previously cited in this prosecution ~~and were not provided~~. Should applicant file an appeal brief in this case and cite these references, the brief will be deemed defective in view of 37 CFR 1.195, which notes "Affidavits, declarations, or exhibits submitted after the case has been appealed will not be admitted without a showing of good and sufficient reasons why they were not earlier presented." Since there is no good cause while the exhibits of these references were not earlier presented, any brief relying upon these references will be defective.

To the extent that these references are relevant, though they will not be entered, Applicant's have not asserted that the current claimed primers are unexpectedly better than any other primers. All He shows is that there can be variability, but even the elements cited by Applicant make it clear that all of the primers He tested were capable of function for the particular purpose. Some may have been better than others, but since the current case has no assertion or argument that the present primers have any secondary considerations relative to other primers, this argument would not overcome the *prima facie* case.

Consequently, the rejections are maintained.